

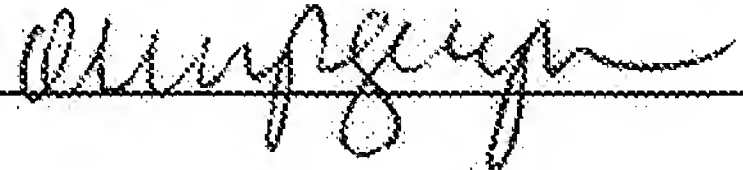
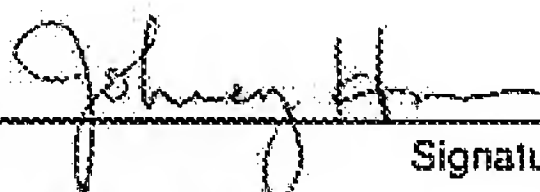
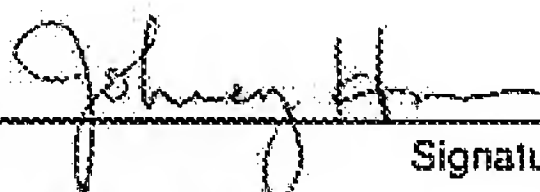
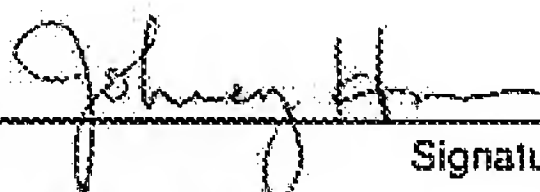
Doc Code: AP.PRE.REQ

PTO/SB/33 (07-09)

Approved for use through 07/31/2012. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) USGINZ00700								
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on <u>August 11, 2010 (VIA EFS)</u> Signature <u></u> Typed or printed name <u>Quyen Nguyen (VIA EFS)</u>	Application Number <u>10/824,936</u>	Filed <u>April 14, 2004</u>								
	First Named Inventor <u>Vahid SAADAT</u>									
	Art Unit <u>3739</u>	Examiner <u>Matthew J. Kasztejna</u>								
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>I am the</p> <table><tr><td><input type="checkbox"/> applicant/inventor.</td><td rowspan="2"><u></u> Signature <u>Johny U. Han</u> Typed or printed name</td></tr><tr><td><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</td></tr><tr><td><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>45,565</u></td><td><u>(650) 242-4217</u> Telephone number</td></tr><tr><td><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</td><td><u>August 11, 2010</u> Date</td></tr></table> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p> <p><input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.</p>				<input type="checkbox"/> applicant/inventor.	<u></u> Signature <u>Johny U. Han</u> Typed or printed name	<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)	<input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>45,565</u>	<u>(650) 242-4217</u> Telephone number	<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____	<u>August 11, 2010</u> Date
<input type="checkbox"/> applicant/inventor.	<u></u> Signature <u>Johny U. Han</u> Typed or printed name									
<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)										
<input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>45,565</u>	<u>(650) 242-4217</u> Telephone number									
<input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____	<u>August 11, 2010</u> Date									

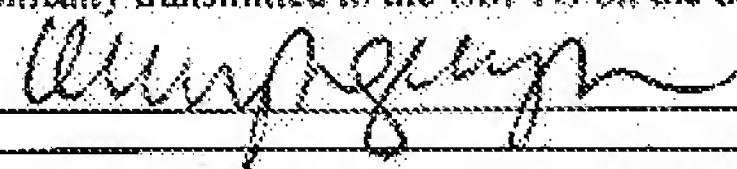
This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

I hereby certify that this correspondence is being electronically transmitted to the USPTO on the date shown below.

Date: August 11, 2010

Signature: _____



(Quyen Nguyen)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/824,936

Confirmation No.: 7289

Filing Date: April 14, 2004

Inventor(s): Vahid SAADAT et al.

Title: METHOD AND APPARATUS FOR OBTAINING
ENDOLUMINAL ACCESS

Examiner: M. Kasztejna

Group Art Unit: 3739

REASONS SUPPORTING PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

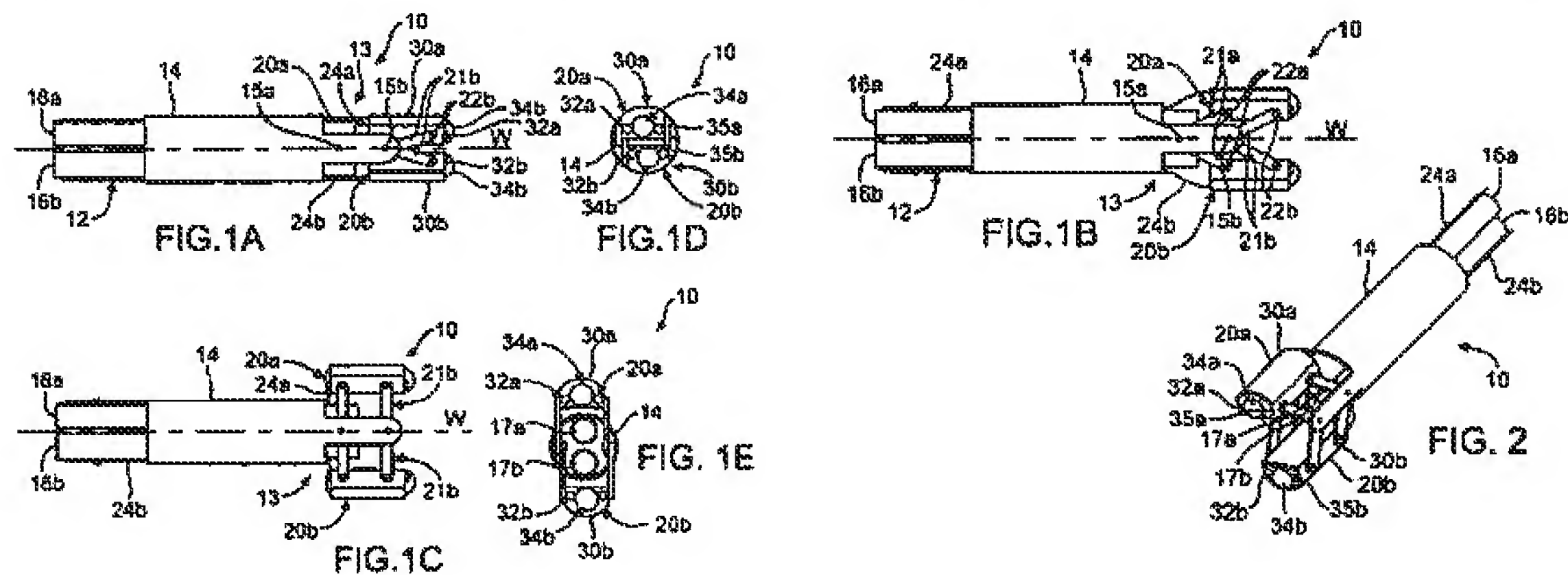
This is in response to the Final Office Action mailed March 11, 2010, in the above-identified United States Patent Application. Filed herewith is a Notice of Appeal and fee, and a petition and fee for a two month extension of time. The Commissioner is authorized to charge any other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. USGINZ00700.

A pre-appeal brief review is requested for the reasons set forth below.

INTRODUCTION

The present application relates generally to apparatus and methods for achieving endoluminal access. The apparatus and methods facilitate introduction of flexible endoscopic instruments during endoluminal procedures. Embodiments of apparatus for performing portions of the claimed methods are shown in FIGS. 1A-E and 2, reproduced below. The illustrated embodiments include an elongate body 12, two working lumens 16a, 16b and two articulating elements 20a, 20b pivotally connected to the elongate body by linkages 21a, 21b. The linkages are each pivotally connected to a first

hinge 22a, 22b on the articulating element and a second hinge 15a, 15b on the elongate body. The articulating elements 20a, 20b articulate from an in-line position (FIGS. 1A, 1D) to an off-axis position (FIGS. 1B, 1C, 1E, 2). Distal openings 17a, 17b of each of the working lumens 16a, 16b are substantially covered by the articulating elements in their in-line positions and are substantially uncovered by the articulating elements in their off-axis positions.



As stated in Appellants' Specification (at paragraph 0032):

Articulating elements 20 off-axis and out of alignment with working axis W exposes distal openings 17 of lumens 16. Once exposed, lumens 16 may be used for passage of diagnostic or therapeutic tools from the proximal to the distal region of apparatus 10, as well as to draw suction, inject fluids, etc. By providing apparatus 10 with elements that articulate, lumens 16 may be provided with larger cross-sectional profiles than otherwise would be possible for a given delivery profile, as compared to apparatus having needed elements that cannot articulate.

ISSUES ON APPEAL

At issue are the following: (a) whether claims 31-33, 36-38, 40-43, and 65-77 should be rejected under 35 U.S.C. § 102(e) as being anticipated by US 2005/0096502 to Khalili ("Khalili"), and (b) whether claims 1-2, 5-9, 19, 23-24, 26-27, and 29-30 should be rejected under 35 U.S.C. § 103(a) as being unpatentable over Khalili in view of USP 5,251,611 to Zehel et al.

ARGUMENT

I. Rejections of Claims 31-33, 36-38, 40-43, and 65-77

In the pending Final Office Action, claims 31-33, 36-38, 40-43, and 65-77 were rejected as being anticipated by the Khalili publication. Appellant traverses these

rejections because the Khalili publication fails to teach or disclose all of the method steps and/or device limitations of the foregoing claims.

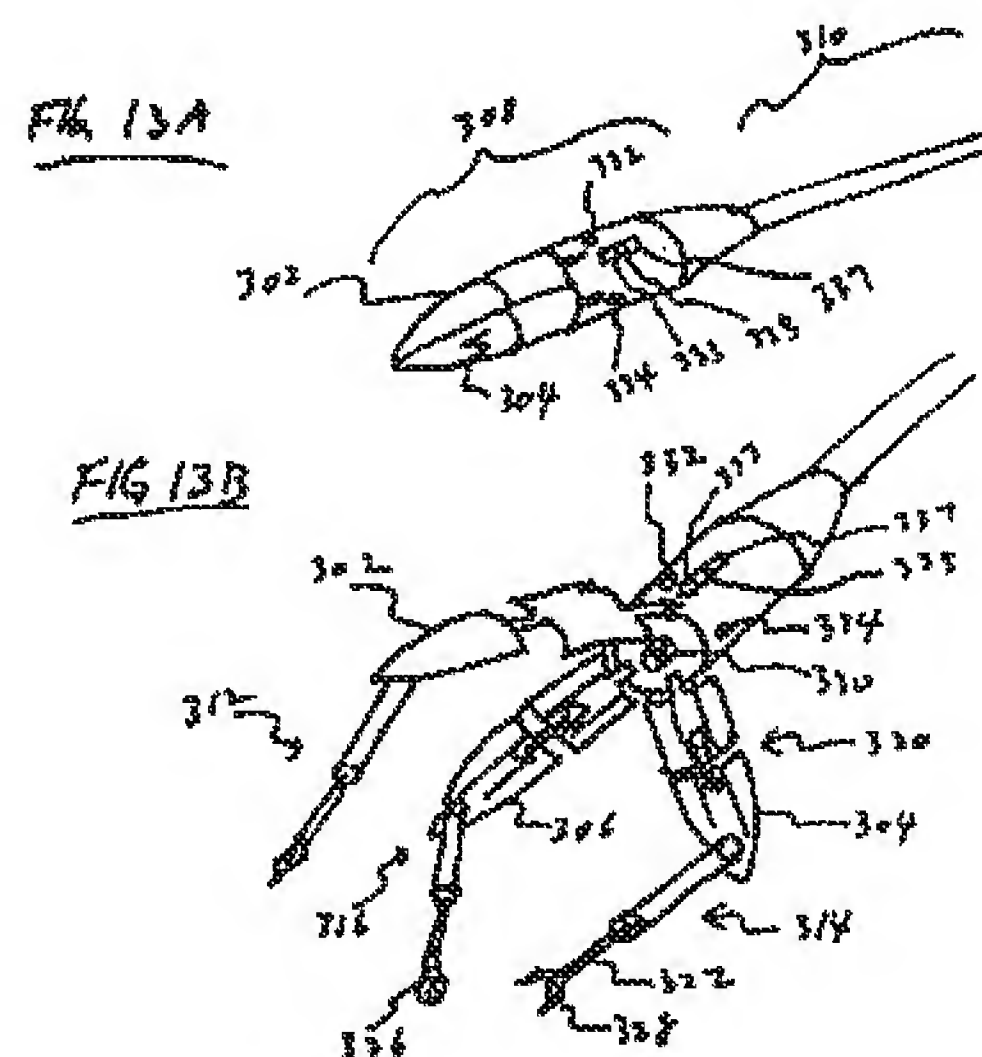
Claim 31 recites a method that includes, *inter alia*, steps of advancing an elongate body having at least one articulatable element disposed at or near a distal region thereof into a body lumen, and the following two additional method steps:

- moving the articulatable element from a position in-line with or adjacent to a working axis of the elongate body to a position out-of-line with the working axis, thereby at least substantially exposing a distal opening of a working lumen provided in the elongate body, and
- passing a diagnostic or therapeutic tool through the working lumen while the articulatable element is maintained in the out-of-line position.

Claim 65 recites an apparatus that includes, *inter alia*, a substantially flexible elongate body, at least one articulating element disposed at or near a distal region of the elongate body, and the following additional limitations:

- at least two working lumens extending through the elongate body; and
- wherein the at least one articulating element articulates from an in-line position to an off-axis position relative to the working axis of the elongate body, and wherein a distal opening of at least one of the working lumens is substantially covered by the at least one articulating element in the in-line position and is substantially uncovered by the at least one articulating element in the off-axis position.

In the rejections of claims 31 and 65, the Office Action (at pp. 3-4) relies upon the FIG. 13A-B embodiment of the Khalili publication, shown below. The Office Action identifies a camera 330 as allegedly corresponding with the “working lumen” recited in claim 31 and with one of the “at least two working lumens” recited claim 65. The Office Action further states that “a distal opening 330 of one of the working lumens is substantially covered by” one of the robotic arms 312-314 in the in-line position and is substantially uncovered by the robotic arms in the off-axis position.



Appellants respectfully disagree with the contention stated in the Office Action that the Khalili camera 330 corresponds with a “working lumen” recited in claims 31 and 65. In particular, Appellants submit that this finding is based upon an unreasonable interpretation of the limitations of claims 31 and 65 identified above. While it is true that claims undergoing examination are to be given their broadest reasonable construction, any such interpretation must be “consistent with the specification” and the claim language must be read “in light of the specification as it would be interpreted by one of ordinary skill in the art.” In re Suitco Surface, Inc., No. 09-1418 (April 14, 2010) (citations omitted). Appellants submit that the constructions of claims 31 and 65 proposed in the Office Action do not satisfy this standard.

The recitation in each of the claims of “a working lumen” or “at least two working lumens” refers to an open space(s), channel(s), or conduit(s) to be used for passage of diagnostic or therapeutic tools therethrough. This interpretation is supported by Appellants’ specification, which consistently uses the terms to refer to such a structure. (See, e.g., ¶ 0002: “The elongate body may also include *a working lumen to facilitate passage of diagnostic or therapeutic tools therethrough*, or for injection of fluids or to draw suction.” See also ¶ 0048: “In FIG. 7, first steerable shaft 82a illustratively is shown with working lumen 86 that extends through the shaft, as well as through cable 84a and elongate body 72’. Exemplary grasper tool 90 *is shown advanced through lumen 86.*”) The claim language itself further supports this interpretation by reciting, in claim 31, a method step of “passing a diagnostic or therapeutic tool through the working lumen while the articulatable element is maintained in the out-of-line position.”

Comparing the embodiment of the Khalili publication relied upon in the Office Action to reject claims 31 and 65, it is clear that the camera 330 does not constitute a “working lumen” as that claim term would be understood by the skilled worker in the context of Appellants’ Specification. It follows that opening the leaflets 312-316 of the Khalili device does not result in “at least substantially exposing a distal opening of a working lumen” as claimed, nor does Khalili teach “passing a diagnostic or therapeutic tool through the working lumen” as also claimed. For these reasons, there can be no anticipation of either of claims 31 or 65 by the Khalili publication.

The Office Action's "Response to Arguments" section suggests (at pg. 10) that Khalili discloses a "working lumen" which houses the camera 330. There is no support in the Khalili publication for this contention. The "Response to Arguments" section also proposes (at pp. 11-12) that "Khalili teaches various other embodiments that also read on claim 31." Each of the proposed grounds for rejection is flawed – e.g., advancing a robotic tool arm through a port (as per Figs. 5-6 and 7a) does not meet the limitation of "substantially exposing a distal opening of a working lumen" – and none establishes that either of claims 31 or 65 is anticipated by the Khalili publication.

II. Rejections of Claims 1-2, 5-9, 19, 23-24, 26-27, and 29-30

Claims 1-2, 5-9, 19, 23-24, 26-27, and 29-30 were rejected as being unpatentable for obviousness over Khalili in view of Zehel. Like claim 65, claim 1 recites an apparatus for obtaining endoluminal access that includes, *inter alia*, "at least two working lumens extending through the elongate body," and "wherein a distal opening of at least one of the working lumens is substantially covered by the articulating element in the in-line position and is substantially uncovered by the articulating element in the off-axis position." As discussed above, the Khalili publication does not describe or suggest a device that meets these limitations.

The Zehel patent does not correct the deficiencies of the Khalili publication. As a result, there can be no prima facie case of obviousness of claim 1 based upon the combination of Khalili and Zehel.


CONCLUSION

In view of the foregoing, the Application is in condition for allowance. The rejections of the pending claims set forth in the Final Office Action should be withdrawn and the claims passed to issue.

Respectfully submitted,

Customer No. 40518

Levine Bagade Han LLP
2400 Geng Road, Suite 120
Palo Alto, CA 94303
Direct: (650) 242-4217
Fax: (650) 284-2180



John U. Han
Registration No. 45,565

Charles C. Fowler
Registration No. 39,675